REMARKS

Claims 1, 4-7, 11-12, 15, 19, and 24 stand rejected as anticipated by U.S. Patent No. 6,009,877 (Edwards). Claims 6, 8, 11-12, 16-17, 19, and 24 stand rejected as anticipated by U.S. Patent No. 5,196,024 (Barath '024). Claims 1-19 and 24 stand rejected as anticipated by U.S. Patent No. 5,112,305 (Barath, et al. '305). Additionally, Claims 1-19 and 24 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claims 1-28 of U.S. Patent No. 6,547,803 (Seward, et al.).

Claim 6 has been amended and Claim 7 has been cancelled. The pending and amended claims are patentably distinct from the cited art.

Applicants' invention, in one configuration, is directed to operating an actuator to cause a needle thereof to move in a substantially perpendicular direction relative to a wall of a vessel to produce an opening therein. A therapeutic or diagnostic agent is delivered from the needle to a target region via the opening in the vessel wall. Applicants' invention, in another configuration, calls for operating an actuator to cause an expandable section thereof to change from a furled state to an unfurled state such that a needle moves from a position inside an actuator body to a position outside the actuator body. The cited art neither discloses not suggests these features of Applicants' invention.

Edwards

Edwards, as shown in Fig. 9B, for instance, discloses a basket assembly 50 including a number of arms 44. The arms are moveable by means of pull wires 80 operated by, for example, a ratchet mechanism. Specifically, when the pull wires 80 are pulled back by a moveable fitting 82 the camber 54 of the basket assembly increases from 54 to 54', increasing the force and the amount of contact applied by the basket assembly to a sphincter wall 26. (See Col. 5, Line 67 to Col. 6, Line 1; Col. 8, Lines 6-14; Fig. 1).

The arms 44 of the basket assembly may include a number of RF (radio frequency) needle electrodes 90 that extend through respective arm apertures 64 in the outer surface of the arms. (See Col. 9, Lines 33-36, 49-54; Fig. 15). The RF electrodes 90 apply RF energy to the surrounding tissue to cause "heating of the tissue due to the absorption of the RF energy by the tissue and ohmic heating due to electrical resistance of the tissue." (Col. 10, Lines 32-34).

A cooling solution 70 or an electrolytic solution 72 may be provided to a treatment site by flowing such fluids through the apertures 64 in the arms. (Col. 7, Lines 44-48; Fig. 26). The cooling solution is used to protect or otherwise reduce the degree of cell damage at a cooled zone 132. The cooling solution also cools all or a portion of the RF electrodes. (Col. 13, Lines 2-13). The electrolytic solution 72, such as saline, solutions of calcium salts, potassium salts, and the like, is used to increase the electrical conductivity of the tissue being treated. (Col. 8, Lines 60-66).

Cooling fluids and electrolytic solutions are not diagnostic or therapeutic agents. Thus, Edwards does not disclose the use of a therapeutic or diagnostic agent.

Edwards also does not disclose the delivery of a therapeutic or diagnostic agent from a needle. Rather, the cooling or electrolytic solution is applied to a treatment area through the ports 64 in the arms 44. The RF needle electrodes 90 only apply electrical energy to the tissue under treatment.

Additionally, the basket assembly 50 of Edwards does not move between an unactuated condition in which an expandable section is in a furled state and an actuated condition in which an expandable section is in an unfurled state. Rather, the camber 54 or the location of the arms of the basket assembly is changed by applying a translational force, for example, from the back of Edwards' device by means of the pull wires 80.

Also, the RF electrodes 90 of Edwards do not move from a position inside an actuator body to a position outside the actuator body. Instead, as discussed, the RF electrodes extend

through the apertures 64 in the arms 44. As such, the RF electrodes, both in the expanded and contracted positions of the arms, are located at the outside surface of the arms.

Therefore, Applicants' invention is patentably distinct from Edwards.

Barath '024

Barath '024 discloses a cutting balloon 2 having a plurality of cutting blades 6 or cutting wires 19 extending along the outside surface of the balloon. (See Figs. 1, 2, and 14). The cutting edges 6, 19 are designed to penetrate a vessel wall 7, 8 when the balloon is expanded so as to make longitudinal cuts with sharp margins in the vessel wall. (Col. 4, Lines 18-21).

Barath '024 does not disclose the use of a needle. Barath '024 also does not disclose the delivery of a therapeutic or diagnostic agent from a needle. Rather, longitudinal cuttings edges are used to make incisions in a vessel wall.

Additionally, Barath '024 does not disclose operating an actuator to cause an expandable section thereof to change from a furled state to an unfurled state such that a needle moves from a position inside an actuator body to a position outside the actuator body. Instead, as discussed, the longitudinal cutting edges 6, 19 of Barath '024 are located on the outside surface of the cutting balloon 2 in both the inflated and deflated states of the balloon.

As such, Applicants' invention is patentably distinct from Barath '024.

Barath, et al. '305

Barath, et al. '305 is directed to an inflatable balloon in which a plurality of tubular extensions 10 are located on a surface 1 of the balloon. The tubular extensions have holes or lumens 11 for the flow of a fluid therethrough. (See Figs. 1 and 3).

In operation, the pressure in the balloon is slowly built up by injection of a fluid at a low flow rate to the point where the balloon surface 1 closely leans against the endothelial surface of

a vessel 15. At this stage, the tubular extensions have not penetrated the vessel wall and a fluid 17 is barely leaking through the lumens 11 of the tubular extensions. As the flow rate and pressure is abruptly increased, the so-called bursting phase, the tubular extensions 10 penetrate the vessel wall and the fluid 17 is propelled into the deeper layers of the vessel wall through the holes 11. (Col. 3, Lines 26-40; Figs 4 and 5). The vessel wall is thus breached by means of the fluid pressure jets exiting the tubular extensions 10.

Barath, et al. '305 does not disclose the use of a needle to produce an opening in a wall of a vessel for delivery of a therapeutic or diagnostic agent. Additionally, the extensions 10 are on the surface of the balloon 1. As such, an expandable section of an actuator is not operated to change from a furled state to an unfurled state such that a tubular extension moves from position inside an actuator body to a position outside the actuator body.

Clearly, Applicants' invention is patentably distinct from Barath, et al. '305

Double Patenting

A Terminal Disclaimer is submitted with this Amendment to eliminate the double patenting rejection.

Information Disclosure Statement (IDS)

An IDS for the subject application was filed on June 26, 2002. Applicants' have not received the initialed Form 1449 for this IDS. Applicants' request that the Examiner provide this form. A copy of that IDS, along with its Form 1449, is enclosed for the Examiner's convenience.

Conclusion

In view of the forgoing, it is submitted that all the claims are now in condition for allowance. Accordingly, allowance of the claims at the earliest possible date is requested.

If prosecution of this application can be assisted by telephone, the Examiner is requested to call Applicants' undersigned attorney at (510) 495-3206.

Please apply any other charges or credits to deposit account number 50-388 (Order No. UCALP026).

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Respectfully submitted,
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